A New Generation of TKI
TAGRISSO can be an important new standard of care for the 1st-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions or exon 21 L858R mutations), as detected by an FDA-approved test.

Unprecedented Efficacy
In the Phase III FLAURA trial, TAGRISSO nearly doubled median progression-free survival at 18.9 months vs 10.2 months for EGFR tyrosine kinase inhibitor (TKI) comparators (erlotinib or gefitinib). TAGRISSO also reduced the risk of progression or death by 54% vs EGFR TKI comparators (hazard ratio 0.46; 95% CI 0.37, 0.57; p<0.0001).

Consistent Results
TAGRISSO demonstrated consistent results across all predefined subgroups, including those with or without brain metastases. Approximately 25% of patients with EGFRm NSCLC have brain metastases at diagnosis, increasing to approximately 40% within two years of diagnosis.

Overall Survival
Overall survival data from the FLAURA trial are immature (25% maturity). The five-year survival rate for patients with metastatic EGFR+ NSCLC remains less than 15%, underscoring the unmet need.

Proven Mechanism of Action
TAGRISSO is a 3rd-generation, irreversible EGFR-TKI designed to inhibit both EGFR sensitizing and EGFR T790M resistance mutations.

Select Safety Information:
• Interstitial lung disease (ILD)/pneumonitis occurred in 3.9% of the 1142 TAGRISSO-treated patients; 0.4% of cases were fatal. Withhold TAGRISSO and promptly investigate for ILD in patients who present with worsening of respiratory symptoms which may be indicative of ILD (eg, dyspnea, cough and fever). Permanently discontinue TAGRISSO if ILD is confirmed.

Please See Reverse for Complete Important Safety Information.
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IMPORTANT SAFETY INFORMATION

- Heart rate-corrected QT (QTc) interval prolongation occurred in TAGRISSO-treated patients. Of the 1142 TAGRISSO-treated patients in clinical trials, 0.9% were found to have a QTc > 500 msec, and 3.6% of patients had an increase from baseline QTc > 60 msec. No QTc-related arrhythmias were reported. Conduct periodic monitoring with ECGs and electrolytes in patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval. Permanently discontinue TAGRISSO in patients who develop QTc interval prolongation with signs/symptoms of life-threatening arrhythmia.

- Cardiomyopathy occurred in 2.6% of the 1142 TAGRISSO-treated patients; 0.1% of cardiomyopathy cases were fatal. A decline in left ventricular ejection fraction (LVEF) ≥10% from baseline and to <50% LVEF occurred in 3.9% of 908 patients who had baseline and at least one follow-up LVEF assessment. Conduct cardiac monitoring, including assessment of LVEF at baseline and during treatment, in patients with cardiac risk factors. Assess LVEF in patients who develop relevant cardiac signs or symptoms during treatment. For symptomatic congestive heart failure, permanently discontinue TAGRISSO.

- Keratitis was reported in 0.7% of 1142 patients treated with TAGRISSO in clinical trials. Promptly refer patients with signs and symptoms suggestive of keratitis (such as eye inflammation, lacrimation, light sensitivity, blurred vision, eye pain and/or red eye) to an ophthalmologist.

- Verify pregnancy status of females of reproductive potential prior to initiating TAGRISSO. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TAGRISSO and for 6 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception for 4 months after the final dose.

- Most common adverse reactions (≥20%) were diarrhea, rash, dry skin, nail toxicity, stomatitis, fatigue and decreased appetite.

INDICATION

TAGRISSO is indicated for:

- The 1st-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- The 2nd-line treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR-TKI therapy.

Please see complete Prescribing Information including Patient Information.